

HEAD CONGESTION FLU SEVERE PE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated GOODSENSE

1174-GDS-2022-0804

Drug Facts

| Active ingredients (in each caplet) | Purposes |
|------------------------------------------------|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 100 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- temporarily relieves these symptoms due to the common cold:
 - nasal congestion
 - headache
 - minor aches and pains
 - cough
 - sore throat
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**

| | |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| adults and children 12 years and over | <ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ do not take more than 10 caplets in 24 hours |
| children under 12 years | <ul style="list-style-type: none">▪ ask a doctor |

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

GOODSENSE®

NDC 50804-274-02

Head Congestion + Flu Severe PE

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

Pain Reliever / Fever Reducer, Cough Suppressant, Expectorant, Nasal Decongestant

For Relief of

- Sinus Pressure
- Headache
- Sore Throat
- Cough
- Chest Congestion

24 CAPLETS

Actual Size

Compare to active ingredients of Sudafed PE® Head Congestion + Flu Severe†

GOODSENSE®

NDC 50804-274-02

Head Congestion + Flu Severe PE

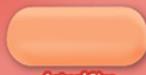
Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

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For Relief of

- Sinus Pressure
- Headache
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- Cough
- Chest Congestion

24 CAPLETS



Actual Size

Compare to active ingredients of
Sudafed PE® Head Congestion + Flu Severe†

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Head Congestion + Flu Severe.

Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-844-705-4384
GoodSense® is a registered trademark of L. Perrigo Company.

Drug Facts (continued)
Other information
 ■ store between 20-25°C (68-77°F) in a dry place
 ■ retain carton for complete product information and warnings
Inactive ingredients
 colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, methocel K100, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Drug Facts (continued)
Warnings
 Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product ■ if a skin reaction occurs, stop use and seek medical help right away. Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash ■ sore throat ■ throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.
Do not use
 ■ with any other drug containing acetaminophen (prescription or nonprescription). ■ if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. ■ if you do not know if your prescription drug contains any of its ingredients
Ask a doctor before use if you have
 ■ high blood pressure ■ liver disease ■ heart disease ■ thyroid disease ■ diabetes ■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor or pharmacist before taking this product. ■ if you have ever had an allergic reaction to this product or any of its ingredients
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.
Warnings (continued)
 ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus) ■ Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin
When using this product do not exceed recommended dosage
 ■ fever gets worse or lasts more than 3 days ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleepiness occur ■ if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Directions
 ■ do not take more than directed (see overdose warning) adults and children ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ 12 years and older ■ ask a doctor ■ children under 12 years

Drug Facts (continued)
Active ingredients (in each caplet) Purpose
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HEAD CONGESTION FLU SEVERE PE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50804-274 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------------|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------------------------------|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | AAA;1134 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|---------------------------------------------------------|------------|--|
| 1 | NDC:50804-274-02 | 2 in 1 CARTON | 08/03/2022 | |
| 1 | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M012 | 08/03/2022 | |

Labeler - GOODSENSE (076059836)

Revised: 10/2024

GOODSENSE